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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 22, 2004

MannKind Corporation

(Exact name of registrant as specified in its charter)

Delaware	**000-50865**	**13-3607736**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(IRS Employer Identification No.)

28903 North Avenue Paine **Valencia, California**	**91355**
(Address of principal executive offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: **(661) 775-5300**

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CRF 240.13e-4(c))

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Section 8 – Other Events

Item 8.01 Other Events

On December 22, 2004, MannKind Corporation issued a press release announcing results from its US-based late phase 2 clinical study of Technosphereâ Insulin. A copy of the press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

Section 9 – Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits

(c) Exhibits.

Number	Description
99.1	Press Release of MannKind Corporation dated December 22, 2004, reporting MannKind's results from its US-based late phase 2 clinical study of Technosphere® Insulin.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MANNKIND CORPORATION

By: /s/ Richard L. Anderson
Name: Richard L. Anderson
Title: Chief Financial Officer

Dated: December 22, 2004

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EXHIBIT INDEX

Number	Description
99.1	Press Release of MannKind Corporation dated December 22, 2004, reporting MannKind's results from its US-based late phase 2 clinical study of Technosphere[â] Insulin.

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MannKind Reports Positive Data from its US Phase 2b Clinical Trial of Technosphereâ Insulin in Type 2 Diabetes Mellitus and Commences First Phase 3 Clinical Trial in Europe

Valencia, California (December 22, 2004) – **MannKind Corporation (Nasdaq: MNKD)** released summary information today on results from its US-based, late Phase 2 clinical study of Technosphereâ Insulin, a pulmonary insulin formulation delivered via its proprietary inhaler to patients with diabetes mellitus. The MannKind pulmonary insulin system rapidly delivers regular human insulin to the bloodstream in a manner that approximates the first phase insulin release spike by the pancreas that occurs almost immediately after the start of a meal in normal, healthy individuals but is lost in patients who develop diabetes. This spike plays an important role in glucose control by signaling the liver to stop releasing glucose into the bloodstream while glucose is being ingested from a meal.

The double-blind, placebo-controlled study was conducted at 21 sites in the United States. Patients who participated in the study were experiencing inadequate control of diabetes determined on the basis of HbA1c results (a measure of glucose control over the preceding three to four months) obtained at the time of screening. All patients received basic diabetes education and performed regular monitoring of blood glucose levels at home prior to randomization. A total of 123 patients (41 women and 82 men) were randomized into either a group that inhaled Technosphere Insulin (doses containing 6 to 48 units of insulin) or Technosphere placebo, in both cases at mealtimes. One hundred seven patients completed the full 12 weeks of treatment with blinded study agents.

Patients that constituted the primary efficacy population (n=90) had a mean HbA1c level of 7.74% at baseline with a range of 6.6% to 10.5%. As part of the study analysis plan, these patients were evaluated in two groups: those with moderately severe elevations of HbA1c levels at baseline of 8.0% and above (values identified by the American Diabetes Association as requiring definitive therapeutic intervention to minimize complications) and those with mild- to moderate elevations of HbA1c levels at baseline ranging from 6.6% to 7.9%.

Patients with moderately severe elevations of HbA1c levels at baseline (n=35; mean HbA1c 8.72%; range 8.0% to 10.5%), who were treated with Technosphere Insulin, experienced a mean reduction of 1.37 percentage points by the end of 12 weeks of

treatment. The difference in reduction of HbA1c levels between the Technosphere Insulin and the placebo treatment groups was highly statistically significant (p=0.0007) in favor of Technosphere Insulin.

Patients with mild to moderate elevations of HbA1c levels at baseline (n=55; mean HbA1c 7.18%; range 6.6% to 7.9%), who were treated with Technosphere Insulin, experienced a mean reduction of 0.43 percentage points by the end of 12 weeks of treatment. The difference in reduction of HbA1c levels between the Technosphere Insulin and the placebo treatment groups was statistically significant (p=0.0447) in favor of Technosphere Insulin.

Overall, in the primary efficacy population, there was a highly statistically significant difference between the two treatment groups (in favor of the Technosphere Insulin group) with respect to the proportion of patients who achieved a reduction in HbA1c levels by the goal of at least 0.6 percentage points (chi-square; p=0.0052). Approximately four times as many patients in the Technosphere Insulin-treated group achieved a final HbA1c level of 6.5% or less as compared to the placebo-treated group.

There were no serious adverse events that were related to the use of the study drug**.** No episodes of severe hypoglycemia occurred in any of the patients treated with Technosphere Insulin. Pulmonary function was assessed by DLco measurements, FVC and FEV1 rates, and there was no clinically significant difference between the 12-week test results and baseline values in the patient group receiving Technosphere Insulin. Importantly, there was also no evidence of treatment-induced insulin antibodies occurring in patients treated with Technosphere Insulin.

Dr. Wendell Cheatham, Corporate Vice President and Chief Medical Officer of MannKind, commented, “This study indicates that Technosphere Insulin can effectively lower blood glucose levels in patients with type 2 diabetes who previously were experiencing inadequate control of their disease. The typical risks of frequent or severe hypoglycemia associated with insulin therapy appear to be minimal with Technosphere Insulin, giving it a potentially significant safety advantage over other therapies.”

Alfred Mann, Chairman and Chief Executive Officer of MannKind, stated further, “In our earlier clinical studies, we observed that the kinetic profile of Technosphere Insulin approximates the first phase insulin release spike of normal, healthy individuals. With these latest observations of no increases in antibodies, no clinically significant changes in pulmonary function and no episodes of severe hypoglycemia in patients treated with Technosphere Insulin, we continue to be optimistic regarding the future of Technosphere Insulin. We are now preparing to submit these results to the United States Food and Drug Administration. In the meantime, we have initiated our first Phase 3 clinical trial in Europe, enrolling patients this week. We are pleased that the Company continues to achieve its intended milestones on or ahead of schedule.”

About MannKind Corporation

MannKind focuses on the discovery, development and commercialization of therapeutic products for diseases such as diabetes and cancer. The Company recently commenced Phase 3 clinical trials in Europe of its lead product, the Technosphere® Insulin System, to study its potential for the treatment of diabetes. This System consists of a proprietary dry

powder Technosphere® formulation of insulin that is inhaled into the deep lung using the Company's MedTone™ inhaler. MannKind believes that the performance characteristics, unique kinetics, convenience and ease of use of its proprietary Technosphere® Insulin System may have the potential to change the way diabetes is treated. For more information on MannKind Corporation and its technology, visit www.mannkindcorp.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements related to our clinical trials and product candidates, that involve risks and uncertainties. Words such as "believes", "anticipates", "plans", "expects", "intend", "will", "goal", "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon our current expectations. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to the progress, timing and results of clinical trials, intellectual property matters, difficulties or delays in seeking or obtaining regulatory approval, manufacturing our lead product candidate, competition from other pharmaceutical or biotechnology companies, our ability to enter into any collaborations or strategic partnerships or obtain additional financing to support our operations, or ability to meet milestones and other risks detailed in our filings with the SEC, including our Registration Statement on Form S-1 and our quarterly reports on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and MannKind undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this release.